



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

MEMORANDUM

OFFICE OF THE
SCIENCE ADVISOR

FROM: Warren E. Lux, M.D. *W. Lux*
EPA Human Subjects Research Review Official (8105R)

TO: Patti Lynn Tyler
Science Advisor, EPA Region 8

SUBJECT: Determination of Exemption under 40 CFR 26.101(b) for Research
Involving Human Subjects

DATE: June 27, 2008

I have reviewed the project cited below according to the requirements of EPA Order 1000.17 Change A1 (**Policy and Procedures on Protection of Human Research Subjects**) and have determined that the survey component qualifies as research involving human subjects that is exempt from EPA Regulation 40 CFR 26 (**Protection of Human Subjects**) by virtue of belonging to category (2) under 40 CFR 26.101(b). The project also has additional research elements for which the regulatory definition of a human subject found at 40 CFR 26.102(f) is not met, as well as elements that qualify as public health practice. Neither of these latter elements is subject to the requirements of EPA Regulation 40 CFR 26. If any changes are made to the project during implementation, however, the applicability of 40 CFR 26 should be reevaluated.

Project Title: *Sampling and Analysis Plan for the BMX Track at
Operable Unit 5, Libby Asbestos Superfund Site, Libby
Montana*

Engaged Entity: EPA Region 8

Project Manager: Kathryn Hernandez

EPA HSRR #: F08-0027P

CC: Kathryn Hernandez
Helen Dawson